

### **REMARKS**

Applicants' express their appreciation for the allowance for Claims 3, 5-13, 16, 17, 19, 20, 22, 23, 25, 27-28. The rejection of Claims 1-2, 4, 14-15, 18, 21, 24, 26 and 29 will now be discussed.

The Examiner's objection is directed to the abbreviations LHRH or GnRH is noted. Applicant is not certain whether the Examiner at some place in this specification or claims is requesting, for instance, the use of "gonadotropin-releasing hormone". Further, input from the Examiner is requested. This could very well be one topic of discussion when one of the applicants and the undersigned attorney hold an interview with the Examiner, most likely during the month of February at the convenience of the Examiner.

### **THE ABSTRACT**

In accordance with the request of the Examiner a revised Abstract is provided on a separate sheet which is attached hereto.

The request to capitalize trademarks is noted. Applicants have carefully reviewed the specification and claims, but can find no instance where a trademark was not capitalized. This question can be reviewed at the interview.

### **DOUBLE PATENTING**

The provisional rejection of Claims 15, 18 and 29 on the ground of obviousness-double patenting is noted. A terminal disclaimer is being provided.

### **REJECTION UNDER FIRST PARAGRAPH OF 35 U.S.C. §112**

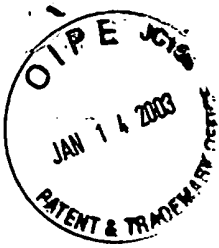
The rejection of Claims 1, 2, 4, 14, 15, 18 and 29 under 35 U.S.C. §112 first paragraph is noted. Applicants submit that there is compliance with the statute.

It is known that sex hormones exert a strong influence on the incidents of cardiovascular disease. See Castelli, W.P. Cardiovascular Disease in Women. Amj Obstet Gynecol. 1988; 158:1553-60. It is also known that a disorder with high testosterone levels is associated with premature atherosclerosis and heart disease. See Guzick et al. Cartoid Atherosclerosis in Women with Polycystic Overy Syndrome; Initial results from a case control study. Amj Obstet Gynecol. 1996; 174:1224-32.

Attention is called to the studies involving finasteride as set forth starting in the last paragraph on page 4 of the Specification, then continuing on pages 5 and 6 of the Specification. The actual results are set forth in a table on page 7 of the Specification.

The foregoing demonstrates that inhibition of the testosterone pathway at two separate points by three different molecules results in a reduction in cardiovascular risk. This is strong evidence.

While an idiosyncratic effect of a particular molecule can never be completely ruled out, the protective effect of finasteride, goserelin and leuprolide must be attributed to their effect on testosterone metabolism. The dutasteride of the present invention demonstrates a similar effect on testosterone metabolism.



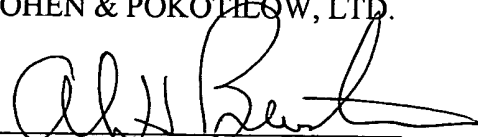
**REJECTION UNDER 35 U.S.C. §112 second paragraph**

It is submitted that these claims are properly worded. This issue can be discussed  
at the interview.

Respectfully submitted,

CAESAR, RIVISE, BERNSTEIN  
COHEN & POKOTILOV, LTD.

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By: 

Alan H. Bernstein  
Registration No. 19,315  
Seven Penn Center - 12<sup>th</sup> Floor  
1635 Market Street  
Philadelphia, PA 19103-2212  
(215) 567-2010  
Attorneys for Applicants  
Customer No. 03000

Enclosures: Terminal Disclaimer and Communication  
Two Petition for Extension of Time  
Abstract of Disclosure